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UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

In Re Bard IVC Filters Products Liability Litigation	No. MD-15-02641-PHX-DGC **PLAINTIFFS' RESPONSE TO DEFENDANTS' MOTION TO EXCLUDE THE EXPERT TESTIMONY OF MARK J. EISENBERG M.D.**

Plaintiffs oppose Defendants' Motion to Exclude the Opinions of Mark J. Eisenberg, M.D. ("Motion" or "Mot.") [Doc. 7291]. Plaintiffs incorporate in this response their Omnibus Statement of Law and Generally-Applicable Arguments in Opposition to Bard's Motions to Exclude Plaintiffs' Experts under Rule 702 and *Daubert* ("Omnibus Mem.") [Doc. 7799], filed contemporaneously herewith. For the reasons set forth herein and in the Omnibus Memorandum, this Court should deny the Motion.

I. INTRODUCTION

Defendants have failed to demonstrate that Dr. Eisenberg's testimony and opinions are inadmissible under *Daubert*[1] and its progeny.

Bard mischaracterizes Dr. Eisenberg's proffered testimony and his expertise and focuses its arguments on areas in which Dr. Eisenberg disclaims expertise (e.g., that he is not an ethics or regulatory expert), rather than acknowledging what he is—a clinical

[1] *See Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993); *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137 (1999).

epidemiologist with expertise in the design, conduct, and interpretation of studies addressing safety and efficacy of medical devices. (Bard Ex. B, 43:4-9 [Doc 7291-2].)[2] Bard also omits Dr. Eisenberg's clinical medicine expertise as an interventional cardiologist, with relevant expertise about patient care and the anatomy and function of the inferior vena cava (IVC) blood vessel (Bard. Ex. A., ¶ 17 [Doc 7291-1]), who treats patients for the conditions for which IVC filters are used (Bard Ex. A ¶ 15), implants "permanent and temporary devices into patients," and "obtains informed consent from patients." (Ex. 2, MDL Dep. at 141:8-20.)

While Bard depicts Dr. Eisenberg's opinions as relating to Bard's ethics, motivations, intentions, and state of mind, this is an unfair characterization of his opinions. Dr. Eisenberg will not testify about any of those topics. Indeed, Dr. Eisenberg does not once in his 47-page report refer to Bard's conduct as unethical. Instead, his opinions relate to the evidence concerning safety and efficacy of Bard's filters, the information that physicians and patients need for proper informed consent and medical decision-making, and an evaluation of Bard's disclosures of the information it had.

Dr. Eisenberg is permitted to testify about his own expectations (and the reasonable expectations of physicians) of Bard to study and disclose risks as related to matters affecting patient safety. He is qualified to testify on this topic, which requires specialized knowledge, and, therefore, will be helpful to the jury. He will not offer opinions that otherwise purport to speak on behalf of all physicians and patients.

Plaintiffs incorporate by reference the Omnibus response containing the legal standards applicable to a motion under *Daubert*, filed contemporaneously herewith.

II. OPERATIVE FACTS

Dr. Eisenberg has expertise both in clinical medicine as an interventional cardiologist and in clinical epidemiology. He has "decades of experience with medical devices and … decades of research experience looking into patient safety." (Ex. 2, MDL Dep. at 151:7–9.)

[2] For simplicity, Plaintiffs cite to Bard's Exhibits throughout this brief.

He is a board-certified physician in internal medicine in the United States and Canada. As an interventional cardiologist, Dr. Eisenberg also is board certified in cardiovascular medicine and interventional cardiology through the American Board of Internal Medicine. He is a fellow of the American College of Cardiology and a fellow of the American Heart Association. In addition to his medical degrees and certifications, Dr. Eisenberg holds a Master's Degree in Public Health from Harvard University, Harvard T.H. Chan School of Public Health, where he was trained in epidemiology and biostatistics. (Ex. 1, *Austin* Dep. Tr., 16:5–15.) Presently, Dr. Eisenberg is a Principal Investigator at the Centre for Clinical Epidemiology, and he is the Director of the M.D./Ph.D. program and the Cardiovascular Health Services Research Group at Jewish General Hospital/McGill University. Dr. Eisenberg is an Associate Member of the McGill Department of Epidemiology, Biostatistics, and Occupational Health. He served for 18 years as Director of Clinical Research for the McGill Cardiology Fellowship Program.

Dr. Eisenberg regularly treats patients with deep vein thromboses (DVT) and pulmonary emboli (PE), which are indications for IVC filters. He routinely implants medical devices. He prescribes a variety anticoagulation medications to patients at risk of PE, which is the preferred alternative to IVC filters in patients that can tolerate anticoagulation. He also treats patients with indwelling IVC filters or patients who will be receiving these filters. (Bard Ex. A at ¶¶ 15, 16.) He, therefore, is qualified to opine on the medical standards for informed consent.

Dr. Eisenberg also explained his expertise as a clinical epidemiologist:

> Besides my clinical activities, I am a clinical epidemiologist and I spend approximately 50% of my time doing cardiovascular research. Much of my research involves the design and conduct of clinical trials, the interpretation of data obtained from clinical trials, the critical analysis of safety issues documented in the medical literature in reports of clinical trials, cohort studies, registries, and administrative database studies. I frequently perform systematic reviews and meta-analyses on a variety of topics including medical devices and drugs. My studies typically evaluate the efficacy and safety of medical devices and drugs via a critical review of the

> published medical literature and, when appropriate, via a statistical pooling of the data.

(Bard Ex. A at ¶ 18.) Further, Dr. Eisenberg has published over 250 articles in peer-reviewed journals and has performed multiple clinical trials, cohort studies, systemic reviews, and meta-analyses. (Bard Ex. A, ¶ 10.)

Dr. Eisenberg applied his expertise in clinical epidemiology and clinical medicine to the issues in this case through his review of: the medical literature concerning safety and efficacy of Bard's filters, Bard's internal documents addressing those issues, defense and plaintiff expert reports, and depositions of Bard employees. This applied methodology set the foundation for Dr. Eisenberg's opinions. Specifically, the focus of Dr. Eisenberg's proposed testimony is (a) "to look at what was, and is, necessary for patient safety with respect to IVC filters" (Ex. 2, MDL Dep. at 273:13–22), (b) to assess and interpret the published medical literature and other lines of evidence pertaining to the safety and efficacy of Bard's retrievable IVC filters (Bard Ex. A, ¶¶ 78-178), (c) to identify "safety signals" based on the evidence available to Bard (*id*., ¶¶ 30, 42, 45, 73, 78-178), and (d) to assess Bard's disclosure of risks with regards to its effect on the adequacy of informed consent (*id*., ¶¶ 25-26, 31, 35, 118, 124, 137, 192).

III. ARGUMENT

Dr. Eisenberg's opinions about the safety and efficacy of Bard's filters and related disclosures to physicians are admissible because he is qualified through his experience as a clinician and epidemiologist to offer these opinions. The opinions will be helpful to the jury because they involve complex terms and statistics that require expert explanation. Further, Dr. Eisenberg's selection of documents was reasonable and does not render his opinion unreliable. Finally, his opinions relate to objective standards regarding informed consent, and are not about other physician's states of mind.

A. Dr. Eisenberg Is Qualified to Offer Opinions about Safety and Efficacy of Bard's Filters and Disclosures to Physicians.

Bard's attack on Dr. Eisenberg as having no relevant expertise that will assist the jury is overly narrow and ignores Dr. Eisenberg's extensive scientific and specialized knowledge in clinical epidemiology and clinical medicine, including his extensive review of Bard filter evidence using that expertise. This expertise is relevant to the opinions that Dr. Eisenberg actually will offer—opinions relating to the safety and efficacy of Bard's filters and the information relevant to patients and physicians, as opposed to the strawmen that Bard has erected—and will assist the jury in understanding the evidence and determining the facts in this case. First, epidemiologic analysis is admissible, and Dr. Eisenberg is qualified to offer it. Second, he is qualified to render opinions about informed consent and patient safety.

1. Dr. Eisenberg's epidemiological analysis is admissible.

As to epidemiology, analyses "that probe the methodological validity of medical studies are not unprincipled or unscientific." *In re Silicone Gel Breast Implants Product Liability Litigation*, 318 F.Supp.2d 879, 895 (C.D. Ca. 2004). At issue before the court in *Silicone Gel Breast Implants* was whether the plaintiffs' epidemiologist was qualified to testify about epidemiological studies. *Id*. at 895. The defendants contended that the expert was not qualified because he previously had never conducted a study examining the relationship between breast implants and cancer and only "reviewed certain articles." *Id*. The court found the defendants' arguments "meritless," *id.*, reasoning that, as an epidemiologist, the witness had "extensive experience in designing, conducting, and analyzing epidemiological studies." *Id*. These credentials were helpful to inquiries regarding "the methodological soundness of [the defendants'] epidemiological data." *Id*. "[T]he methods of epidemiology are fundamentally the same" regardless of the subject matter, so the fact that the expert specialized in psychiatric epidemiology did not preclude him from providing opinions regarding cancer epidemiology. *Id*. The court determined that the expert was "certainly qualified to evaluate and explain the available

epidemiological evidence" given "the facts and the liberal construction of expert qualifications FRE 702 requires." *Id*.

Here, like the expert in the silicone implant case, Dr. Eisenberg's experience includes "more than 20 years of research using epidemiologic tools" (Ex. 2, MDL Dep. at 102:16–22), including assessing complication rates and safety signals (Ex. 1, *Austin* Dep. Tr., 88:8–23), and "clinical trials, cohort studies, case series, case reports, statistics, biostatistics, limitations of studies bias and confounding, ideas like using databases like the MAUDE database, what they can be used for and what they can't be used for, statistics that are used when looking at, for example, in vitro testing." (Ex. 2, MDL Dep. at 271:10–18.) Dr. Eisenberg explained that he is "quite experienced in looking at the totality of the evidence from multiple sources" to determine whether a safety signal is clinically significant. *Id.* Additionally, his experience in clinical epidemiology is "very directly related to the kinds of issues that were looked at in this case." (Ex. 2, MDL Dep. at 270:17–19.) He has performed focused epidemiological research on IVC filters (*id*. at 273:13–22) and has extensive experience in designing, conducting, and analyzing epidemiological studies. In short, he is "certainly qualified to evaluate and explain the available epidemiologic evidence"; his credentials are relevant to the epidemiological inquiries at issue in this case. *See In re Silicone Gel Breast Implants*, 318 F.Supp.2d at 895.

2. Dr. Eisenberg is qualified to render informed-consent and patient-safety opinions.

Dr. Eisenberg also is qualified to offer opinions about the medical standards for informed consent based on his clinical experience, including routine implantation of medical devices and treatment of patients with IVC filters or who are candidates for their placement. *Mettias v. United States*, No. 12-00527 ACK-KSC, 2015 U.S. Dist. LEXIS 27561, at *7 (D. Haw. Mar. 6, 2015) (holding expert qualified to testify about informed consent regarding obesity treatment where expert was "not a medical doctor or a licensed surgeon, and does not have any clinical experience performing bariatric surgery or

otherwise caring for bariatric surgery patients."); *c.f. Niles v. Owensboro Med. Health Sys.*, No. 4:09-CV-00061-JHM, 2011 U.S. Dist. LEXIS 81807, at *6 (W.D. Ky. July 26, 2011) (expert testimony regarding informed consent "will assist the jury").

B. Dr. Eisenberg's Testimony will be Helpful to the Jury.

In addition to being qualified to offer testimony about IVC filter safety and efficacy and the adequacy of information given to physicians, Dr. Eisenberg's testimony will assist the jury because he is using specialized knowledge about complex scientific information and medical standards for informed consent. Bard's various characterizations of Dr. Eisenberg's opinion are a distortion of what he intends to say. His opinions are neither "ethics" opinions, "narrative," "common sense," nor relating to Bards "motives" or "state of mind".

First, he is not offering an ethics opinion. Rather, his testimony focuses on what Bard knew about complications and risks with its IVC filters and what doctors and physicians expect a company to do, and disclose, to effectuate proper informed consent about the risks and benefits of a device.

Second, what Bard describes as "narrative" testimony by Dr. Eisenberg, is in fact an evaluation of what Bard knew and when it knew it, and whether the information available to Bard was information that would be relevant to physicians. It is a discussion of a subset of Bard's internal documents pertaining primarily to safety signals and follow-up, internal standards, disclosure of risks, and testing. This provides an important factual background for understanding his opinions, explains the context and chronology, and provides much of the foundation for and basis of his opinions.

Third, challenges to "narrative" testimony can be made only in context at trial; this argument is premature and not appropriate for a *Daubert* analysis.

Fourth, opinions that Bard claims are "common sense" require specialized knowledge. Just because they may be obvious to Dr. Eisenberg does not render them unhelpful or inadmissible. The meaning and significance of these documents are not self-explanatory or obvious to a lay person, and had Dr. Eisenberg not included these opinions,

Bard would likely be arguing that he had not sufficiently disclosed the bases for his opinions. *Minix v. Canarecci*, 597 F.3d 824, 835 (7th Cir. 2010) ("The expert must explain the methodologies and principles supporting the opinion.").[3]

Finally, Dr. Eisenberg will not testify about Bard's "state of mind" or "motives."[4]

1. Bard's knowledge about filter complications rely on complex facts and relate to warnings, not ethics.

Contrary to Bard's assertion that Dr. Eisenberg's opinions are "personal" about "ethical and moral responsibilities," (Mot. at 3), Dr. Eisenberg should be allowed to testify, within the scope of his specialized knowledge, regarding what information physicians need to obtain informed consent from their patients and concerning what response to safety signals is needed for patient safety.

In this regard, Dr. Eisenberg testified that he relies on his more than twenty years of experience as a physician, "decades of experience with medical devices," and "certainly decades of research experience looking into patient safety" to know what physicians need to know from a manufacturer to obtain informed consent and what steps must be taken in response to safety signals in order to improve patient safety. (*See* Ex. 2, MDL Dep. at 151:7–9; 275:10–15; Bard Ex. A, ¶¶ 119, 137, 197, 202, 207.) More specifically, Dr. Eisenberg cited in his report to objective standards by the American Medical Association, The American College of Radiology, the Society of Interventional Radiologists, and by Bard, itself, pertaining to informed consent (Bard Ex. A, ¶¶ 24-28, 42, 45), and he is knowledgeable about what a reasonable physician would need to know regarding the risks of medical devices to obtain informed consent based on his own experience (e.g., reading professional literature, attending conferences, consulting with

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[3] Fed. R. Civ. P. 26 and Fed. R. Evid. 702 require an expert to disclose the information upon which he relies. Plaintiffs also incorporate by reference the arguments made in their response to the motion to exclude Dr. Kessler's testimony. (See Section B, regarding opinions characterized as "narrative".)

[4] Plaintiffs also incorporate by reference the arguments made in their response to the motion to exclude Dr. Kessler's testimony. (See Section E, regarding opinions characterized as relating to "ethics" and "corporate intent".)

colleagues). (*Id*., ¶ 55; Ex. 2, MDL Dep. at 70:16-71:5.) "When a physician obtains informed consent from a patient, it's critically important that they have the safety information. They cannot get informed consent from a patient unless they actually have the correct safety information to present to the patient." *Id.* This testimony in no way purports to provide an opinion regarding Bard's ethical and moral responsibilities.

The doctrine of informed consent is premised on "the fundamental principle that a competent individual has a right to determine what shall be done with [his or her] own body." *Haberson v. Parke Davis, Inc*., 746 F.2d 517, 522 (9th Cir. 1984) (*citing Smith v. Shannon*, 100 F. Supp. 2d 26 (D. Wa. 1983)). To permit this determination, a health care provider is required to provide the individual "with sufficient information to make an intelligent decision." *Haberson*, 746 F.2d at 522. It is, and has been, Dr. Eisenberg's testimony that Bard has interfered with physicians' ability to provide their patients with information to make intelligent decisions because Bard did not provide sufficient information regarding risk, particularly the complication rates of adverse events, to physicians. *Id*. at 86 ("relevant medical information should be disclosed to a patient, but the physician needs to know it and, in order to know it, they have to get it from somewhere.").

Further, in his report, Dr. Eisenberg delineates that the standards that underlie his opinions regarding safety signal monitoring and follow up, including risk disclosure to physicians by medical device manufacturers "form the foundation of our medical system, are essential for informed consent and patient safety, and constitute generally accepted standards for pharmacovigilance." (Bard Ex. A; ¶¶ 42, 99, 106.)

Moreover, Bard has testified to its "obligation to disclose to the doctors who are using its medical devices all information relating to its products that those doctors would reasonably need to know in order to make determinations regarding whether to use the product (Ex. 3, MDL Dep. Tr., DeCant (Bard VP, Research and Development) 304:10–17), including the risks of the product (Ex. 4, MDL Dep. Tr., DeFord (Bard Senior VP, Science, Technology, and Clinical Affairs) 396:2–17), where the data is relevant and

statistically significant (Ex. 5, MDL Dep. Tr., Ganser (Former Bard VP, Quality, Environmental Sciences, & Safety,) 68:9–21).

Dr. Eisenberg's opinions are based on objective standards and his expert interpretation of them; Bard's challenges should be made through cross examination. *Primiano v. Cook*, 598 F.3d 558, 561 (9th Cir. 2010).[5]

2. Testimony about internal documents can assist the jury when the facts are complex.

Testimony that relates to complex facts is allowed even if it is characterized as "narrative," and Bard's reliance on merely persuasive authority ignores Ninth Circuit case law permitting experts to provide factual summaries of corporate documents involving complex matters. *See Pooshs v. Philip Morris, USA, Inc.*, 287 F.R.D. 543, 553 (N.D. Ca. 2012).

In *Pooshs*, the court qualified the circumstances in which factual narratives of corporate documents are permissible, holding that while an expert epidemiologist's review of corporate documents was not relevant to the corporation's "knowledge and intent," his testimony was relevant to scientific theories within the scope of his expertise. *Id*. Thus, the court allowed the expert to provide factual narratives of internal documents that "discuss complex scientific theories." *Id*.

A layperson cannot be expected "to determine intelligently and to the best degree" the concepts of "internal monitoring," "adverse reports," and "complication rates" without assistance from an expert like Dr. Eisenberg. *See U.S. v. Finley*, 301 F.3d 1000, 1013 (9th Cir. 2002) (reversing exclusion of expert testimony "seemingly based on common sense"; noting "[w]e must be cautious not to overstate the scope of the average juror's common understanding and knowledge"); *Bryant v. Wyeth*, No. C04–1706 TSZ, 2012 WL 12844751 (W.D. Wa. Aug. 22, 2012) (expert's narrative testimony allowed where the "great majority of documents in this case are complicated and references those documents

[5] Bard's focus on whether there are standards that are "binding on Bard" also misses the point. The applicable standards are those required for informed consent and the information Bard had but did not pass on to physicians.

may or may not support are the legitimate subject of expert testimony"); *Goldenson v. Steffens*, No. 2:10–cv–00440–JAW, 2013 WL 682844 (D. Me. Feb. 25, 2013) (expert's narrative testimony allowed where it included explanation of a complex concept "in terms a jury might understand"); *Deutsch v. Novartis Pharm. Corp.*, 768 F. Supp. 2d 420, 443 (E.D.N.Y. 2011) (expert's review of defendant's internal documents allowed where testimony explained "certain risks and whether such information would have been useful to doctors. . . . even if some of those documents do not require expert knowledge.").

As in *Pooshs*, Dr. Eisenberg's proposed testimony discussing Bard internal documents provides a contextual- and fact-based foundation (and basis) for his opinions and falls within the scope of his expertise as a clinical epidemiologist and interventional cardiologist. The facts and concepts involved are complex, and jurors will be unable to grasp concepts without training in clinical epidemiology, statistics, etc. When courts exclude narrative opinions, it is not because the narrative is a summary of facts or a compilation of documents, it is because the narrative is based upon the review of uncomplicated facts, which do not require expertise. *See, e.g., In re Rezulin Prod. Liab. Litig.*, 309 F. Supp. 2d (531 (S.D. New York 2014) (expert testimony excluded because jurors "equally capable" of drawing inferences from "uncomplicated facts").

Here, jurors will be aided by Dr. Eisenberg's testimony, in "determin[ing] intelligently, and to the best degree," *Finley*, 301 F.3d at 1013, the meaning and significance of terms and concepts referenced, including: "reasonable clinical work," "clinical trials," "safety signals," "increased complication risks," "fracture risks," "migration risks," and "tilt risks." (Bard Ex. A ¶ 45.) Nor can a jury interpret, without help, Bard's internal standards for determining when a device is performing unacceptably, (Bard Ex. A at ¶¶ 47, 57), and terms and concepts such as: "actual versus statistically derived frequency of potential hazard", how rates are derived (¶ 47), permanent versus retrievable filters, clinical data summaries, the significance of a multicenter study, complication rates, Bard's internal tracking, and failure rates (¶ 57).[6]

[6] Remarkably, Bard has not provided to *any* of its own experts *any* of its internal

3. Even if the testimony is "narrative," it is properly challenged at trial, not under *Daubert*.

Bard's objection to what it purports to be "narrative" testimony also is not properly raised under *Daubert*. "The objection that testimony is 'narrative' is an objection to form, foundation or responsiveness, and must be presented at trial—as no question is now before the Court to which objection can be made." *In re Actos Prod. Liab. Litig., MDL No. 02299, Memorandum and Ruling: David A. Kessler, M.D., W.D. La., Doc. # 3855, at 18 (January 10, 2014). See also,* MDL Judge Herndon's similar reasoning that the proper avenue for challenging "narrative testimony" is at trial, rather than via Rule 702:

> As to defendant's argument regarding narrative testimony, the Court has broad discretion over the mode and order of examining witnesses and presenting evidence and may allow testimony in narrative form at trial if the Court finds that it would be helpful to the jury. [Citations omitted]. ... Such matters will be decided at trial in context specific situations and will be ruled upon then.

In re Yasmin and YAZ (Drospirenone) Marketing, Sales Pract. & Prod. Liab. Litig., CMO # 47, 2011 WL 6302287, at 13. Similarly, in *Wells v. Allergan*, 2013 WL 7208221 (W.D. Okla. Feb. 4, 2013), the court held that testimony about underlying facts provided useful context and may otherwise be challenged at trial: "To the extent the facts relied upon by [the expert witness] are relevant and not cumulative," the expert witness "may include them in his testimony. ... Defendant may object at trial if [the expert] appears to be simply regurgitating facts, rather than using relevant facts as context for his expert opinions." *Id. at 2*. (The expert at issue in these cases was Dr. Kessler, one of plaintiffs' experts in the Bard IVC filter litigation.)

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documents, including those assessing the safety "crisis" of its retrievable IVC filters. At the same time, Bard seeks to prevent plaintiffs' experts from relying on these documents to support their opinions and to help the jury understand the meaning and significance of these documents.

4. Dr. Eisenberg's testimony that purportedly is "common sense" requires specialized knowledge.

Although Dr. Eisenberg used the words "common sense" at his deposition, the utterance of magic words, such as "common sense" and "lay person" do not mean that the opinions should be excluded. Something that is "common sense" to a doctor is only obvious because of his or her specialized training. It does not change the fact that the issues here are complex, and jurors need assistance from experts to understand them. The Ninth Circuit has recognized "the importance of expert testimony when an issue appears to be within the parameters of a layperson's common sense, but in actuality, is beyond their knowledge." *U.S. v. Finley*, 301 F.3d 1000 (9th Cir. 2002). As such, the Ninth Circuit has reformulated the Rule 702 inquiry, guiding courts to evaluate the opinion wholly and assess each challenged opinion against the following standard: "whether the untrained layman would be qualified to determine intelligently and to the best degree, the particular issue without enlightenment from those having a specialized understanding of the subject matter involved. *Finley*, 301 F.3d at 1013 (*citing United States v. Shay*, 57 F.3d 126, 133 (1st Cir. 1995)).

Bard's partial quote of Dr. Eisenberg's deposition testimony ("I think that you don't need to be an expert to read some of these internal Bard documents…I think any layperson would recognize that"), omits his later clarification:

> [W]hen you read internal company documents … there are things that do not require particular expertise to understand. But let's face it, this whole area is dealing with things that a lay person could not understand, that you need to be a medical expert of some sort in order to even know what an IVC filter is, to know what tilt, to know what perforation, embolization, fracture… In order to know about relative risk and statistically significant differences you need to have some epidemiologic biostatistical background… To…look at the totality of the internal documents and see how the company dealt with the FDA, for example, you would need somebody who was an expert… So … while there are … isolated communication[s], some of them a lay person might be able to read… Other internal documents you clearly need different types of expertise.

(Ex. 1, *Austin* Dep. Tr., 118:3–119:24.) Dr. Eisenberg also testified at his MDL deposition about the specialized knowledge required to properly understand most corporate documents:

> … many terms that are used in the corporate documents that would not be readily intelligible to a juror who is not familiar with [IVC] filters, [or] with the MAUDE database, …[or] with in vitro testing, [or]… with statistics. … I think a juror would understand if it was interpreted and put in context by an expert, and I am talking about what the history, what's the background, what the temporal nature of what went on, what were the exact design changes to the IVC filter, what does the medical literature mean, … what is a cohort study, what is a clinical trial, what is a retrospective study. So these are all terms and concepts that people can readily understand if it is presented to them by an expert, but it's not readily … understandable … without getting into context.

(Ex. 2, MDL Dep. at 268:15–269:11.)

Even if some of the documentary evidence could be understood by a lay person,[7] if a juror would not be able to fully understand the evidence as a whole without testimony from a person with "specialized understanding of the subject matter involved," *Finley*, 301 F.3d at 1013 (*citing United States v. Shay*, 57 F.3d at 133), the testimony should be allowed. Moreover, Dr. Eisenberg should be permitted to testify about Bard's internal policies, and compliance with or departure from its policies, as long as the jury is allowed to draw its own factual conclusions. *See Deutsch v. Novartis*, 768 F. Supp. 2d at 443 (expert allowed to testify about corporate conduct, "regardless of whether he has expertise in the inner workings of pharmaceutical companies or regulatory agencies.").

5. Dr. Eisenberg will not offer opinions about Bard's "ethical responsibilities," "motive," or "state of mind."

While testimony purely directed at a party's subjective intent, motive, or state of mind may be excluded, to the extent an expert contextualizes facts that allow a jury to draw inferences, those opinions are allowed. *Yates v. Ford Motor Co.*, No. 5:12-CV-752-FL, 2015 U.S. Dist. LEXIS 69739, at *12-13 (E.D.N.C. May 29, 2015) ("Plaintiffs' experts will be permitted to opine on whether defendants' internal documents ... includes

[7] Even if true that jurors could understand some of the information without help, Bard does not point to a single document that purportedly requires no specialized knowledge.

information regarding the hazards of asbestos or proper methods to prevent asbestos disease."); *c.f. Pension Comm. of Univ. of Montreal Pension Plan v. Banc of America Secs., LLC*, 691 F. Supp. 2d 448, 467 (S.D.N.Y. 2010) ("Although some of [the expert's] testimony walks a fine line between opining on what investors would customarily assume and what Plaintiffs actually did assume, so long as [the expert] refrains from opining on the actual state of mind of the Plaintiffs, his opinions on these matters are admissible.").

Here, Dr. Eisenberg's opinions about Bard's shortcomings are tied to objective standards that are based on his specialized knowledge, training, and clinical experience. As described above, Dr. Eisenberg treats patients, including those who have filters implanted, and implants medical devices himself. His opinions are regarding what he expects "as a physician with patients who are candidates for IVC filters," (Bard Ex. A at ¶ 34), and are based on his "experience as a physician and from conferences and other venues where physicians express their opinions ... [and] established and accepted objective standards referenced above, including Bard's internal standards." (*Id.* at ¶ 55.) Dr. Eisenberg cites as the underlying principal in these opinions "the reasonable expectations physicians have of medical device companies ... to allow physicians to properly and completely fulfill their obligations of informed consent as well as decisions by physicians in making appropriate therapeutic decisions on behalf of their patients ... [and] expectations of what a reasonable patient would want and need to know in the same or similar circumstances." (*Id.* at ¶¶ 23-26 (citing and quoting the AMA code of Medical Ethics—Chapter 2, the AMA code of Medical Ethics' Opinion 8.08 on informed consent, and the ACR-SIR Practice Guidelines on Informed Consent for Image-Guided Procedures).)

In re Trasylol is distinguishable because in that case the expert opinion about what the company "should have" done was not tied to any objective standard. 2010 WL 1489793, at *8 (excluding opinion about what defendant "should have" done because it reflected the expert's "subjective beliefs and personal views and <u>does not rest on knowledge</u>") (emphasis supplied). As in *Deutsch*, expert testimony may be helpful in

"drawing inferences that may not be apparent without the benefit of experience or specialized knowledge." *Deutsch*, 768 F. Supp. 2d at 443. Dr. Eisenberg is not a regulatory expert and, therefore, does not offer opinions on Bard's regulatory obligations. However, he does and should be allowed to testify about what follow-up to safety signals was required for patient safety. (Bard Ex. A, ¶¶ 119, 137, 197, 202, 207.) Plaintiffs will offer regulatory experts (Drs. Kessler and Parisian) to address regulatory requirements. Regarding "ethics," Dr. Eisenberg only mentioned ethics in his deposition testimony when Bard's counsel asked him about it. (E.g., Ex. 2, MDL Dep. at 43:21–23.) Even when asked, Dr. Eisenberg's response most often was that he did not have an opinion on ethics. In his report, Dr. Eisenberg offers no opinions that Bard's conduct violated ethical standards. To make the record clear, Plaintiffs stipulate that, at trial, Dr. Eisenberg will not offer opinions on Bard's ethics.

C. Bard's Objections to How Documents Were Selected Lack Merit.

Bard also objects to Dr. Eisenberg's focus on what Bard describes as a small number of internal documents, but this objection lacks merit. First, Bard does not accurately describe his selection of documents; and second, an appropriate challenge to document selection should be made via cross-examination, not *Daubert*.

First, as to the inaccuracy of Bard's contention, Dr. Eisenberg made clear in his report that he instructed plaintiffs' counsel on the topics in which he was interested. (*See* Bard Ex. A, ¶ 51, n. 2 ("I obtained internal Bard documents from plaintiffs' counsel. I understand that there are several million documents produced by Bard in this litigation. In my meetings and conversations with counsel ..., I informed them of my interest in certain categories of documents bearing on those issues.").) He also testified about how the documents he reviewed were selected:

> … I was provided with a Drop Box of a huge number of corporate documents from which I could … pick and choose. My attention was drawn to certain corporate documents by the Lawyers as well. I would say also, in my reading through this case, I have also gone back to see other documents that perhaps were referred to in other expert reports.

(Ex. 2, MDL Dep. at 61:10-20.)

Dr. Eisenberg also testified, that he took it upon himself to determine which documents to review. *Id.* at 62:20–64:19. In particular, Dr. Eisenberg testified that if he had found documents that did not support his conclusions, he would have included those documents in his report. *Id.* He further testified:

> I looked at the documents to see … when were the different design modifications made to the various filters, what kinds of analyses were being done by Bard, what were the results of those analyses. … I looked at things like [Health Hazard Analyses]. … I was … looking at the documents to see what the time sequence of what happened, and what types of analyses were done, and when they were done, what the results were, what did they do with those results.

(*Id.* at 62:20–64:19.)

Second, if Bard believes that there are other documents that contradict the ones Dr. Eisenberg relied on and addressed, the proper and preferred remedy is cross-examination. *Daubert*, 509 U.S at 596 ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence."); *see also Hemmings v. Tidyman's Inc.*, 285 F.3d 1174, 1188 (9th Cir.2002) ("[I]n most cases, objections to the inadequacies of a study are more appropriately considered an objection going to the weight of the evidence rather than its admissibility. Vigorous cross-examination of a study's inadequacies allows the jury to appropriately weigh the alleged defects and reduces the possibility of prejudice.") (internal citation omitted), *cert. denied*, 537 U.S. 1110 (2003); *accord*, *Kennedy v. Collagen Corp.*, 161 F.3d 1226, 1230-31 (9th Cir.1998).[8] Moreover, Bard has

[8] A close look at the paragraphs cited in Bard's motion belie the claim that they are "out-of-context summaries of a handful of lawyer-selected documents" that "sound[] more like closing argument." (Bard Brief. at 1:17-18, 14:24-26.) Bard takes specific issue with paragraphs 45, 47, 57, and 61. (*Id.* at 3:19-24.) Paragraphs 45 and 47 are evidence of Bard's internal standards regarding device safety, which are then applied to the available evidence. Paragraph 47 provides information about one of Bard's Standard Operating Procedures that Dr. Eisenberg opines "sets a minimum standard for when a device failure rate is unacceptable and must be corrected." (Bard Ex. A at ¶ 49.) He then applies the standard to the available data, and provides an expert opinion that the rate of failures for Bard's filters was "unacceptable" under Bard's own standard. (*Id.* at ¶ 88-90.) This

not pointed to any relevant documents from among the millions that Dr. Eisenberg purportedly ignored. The simple existence of additional documents—even if they number in the millions—does not aid in the inquiry as to what Bard knew and when it obtained certain information. In other words, documents providing evidence of Bard's knowledge may be used for that purpose regardless of what other documents Bard may wish to use during cross examination or in support of its proofs at trial.

D. Dr. Eisenberg Does Not Seek to Offer Impermissible Testimony Regarding the Opinions of All Physicians

Dr. Eisenberg's opinion about informed consent is admissible because he does not speak about other physicians' states of mind, but about standards of medical care.

It is not impermissible testimony for an expert physician with specialized knowledge to opine about what all physicians need to carry out their duties as physicians. In *Deutch v. Novartis*, the court permitted the plaintiff's expert to testify to his interpretation of whether certain information contained in internal documents "would have been useful to doctors" and to the "type of information a doctor expects to receive from the company." 768 F.Supp.2d 420 (E.D.N.Y. 2011). An article in which Bard's expert, Dr. Feigal, was a second author, set out the very standards about which Dr. Eisenberg intends to testify. In the article, Dr. Feigal agreed that that "physicians must know about the performance features of any device they recommend for a patient, so that they can carry out their ethical obligation of obtaining informed consent. ... [a]nd ... patients have a right to obtain product information so that they can make informed decisions about risks and benefits and can understand what expectations are reasonable." (Ex. 7; Myerburg, "Life-Threatening Malfunction of Implantable Cardiac Devices," N. ENG. J. MED., 354; 22 2309 (2006).) The authors explained that expert review is required to properly

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opinion is neither disjointed nor amenable to closing argument without the help of a jury to understand it. Paragraph 57 compares failure rates between Bard's SNF filter and the Recovery, G2, G2X, and Eclipse, central issues in this case, and again cannot be properly interpreted without an expert explanation. Finally, paragraph 61 mentions that the SNF was a predicate for the Recovery filter and Bard claimed that they were substantially equivalent. This, again, is a central issue in the case, and information necessary to understand Dr. Eisenberg's opinions.

evaluate the applicable standards: "engineering performance standards are insufficient benchmarks without evaluation by experts of the possible effects on individual patients." *Id.* at 2010.

While Bard focuses on whether Dr. Eisenberg can testify to how other physicians would react to the complication rates, the principle focus of Eisenberg's testimony is what physicians need to perform their duties, particularly to provide informed consent, as argued above. This testimony is based on the medical standard of care and on objective standards referenced in Dr. Eisenberg's report. (Bard Ex. A at ¶¶ 23-26.) Based on his training and experience, he does know the information "all" physicians need to obtain informed consent. (Ex. 2, MDL Dep. at 82:24–83:4 ("So the physician can't … really obtain true informed consent unless they are knowledgeable about the risks and benefits associated with the procedure and the device. That's dependent on having that information available to them.").)

Bard's own consultant, Dr. Christine Brauer, testified that physicians' expectations about safety and performance of a product are "important." (Ex. 6, Christine Brauer Dep. Aug. 2, 2017, Tr. at 334:4-14.) *See In re Guidant Corp. Implantable Defibrillators Prods. Liab. Litig.*, No. 05-1708 (DWF/AJB), 2007 U.S. Dist. LEXIS 48200, at *33 (D. Minn. June 29, 2007) (expert "qualified to opine generally on the expectations of the medical community. ... opinions as to what he believes the medical community's expectations are of ICD manufacturers are presumptively admissible, subject to proper foundation being laid at trial. Guidant's arguments as to [expert's] lack of experience in medical device manufacturing, FDA requirements, and polyimide go to weight rather than admissibility.").

Moreover, if Bard intends to rely on the learned-intermediary doctrine as a defense, then it places a legal standard at issue, which must, therefore be a universal standard that does not vary from physician to physician. The standard—and Bard's adherence to it—therefore, must be established via the opinions of competent, experienced physicians. These opinions, therefore, are admissible.

IV. CONCLUSION

Dr. Eisenberg should be allowed to testify about the safety and efficacy of Bard filters, what Bard knew, and whether the information was relevant to physicians and patients for informed consent. These are all proper subjects for expert testimony by a practicing physician who is qualified to offer them. This Court should deny Bard's Motion to disqualify Dr. Eisenberg.

RESPECTFULLY SUBMITTED this 27th day of September 2017.

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CERTIFICATE OF SERVICE

I hereby certify that on this 27th day of September 2017, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing.

/s/ Gay Mennuti